

**Minutes of TES Weekly Status Meeting (PM-8451)**  
**February 17, 2003**  
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**Participants**

**Philip Morris**

Robin Kinser

Bettie Nelson

Candace Adams

Jan Oey

Hans-Juergen Roethig

Mohamadi Sarkar

**MDS**

Kimberly Prchal

**Covance**

Eric Larson

Jill Schultz

Mary Westrick

The following items were discussed:

**Stratification Cells/Performance Markers**

The stratification table will be updated later this week, as Mary Larson was out sick. However, the database includes 3,776 completed subjects and subjects with future appointments.

Hans requested that we provide an updated timeline that includes information on the completion of enrollment and sample analysis.

**ACTION: J. Schultz/M. Larson**

**Recruitment for Low Tar Group**

It was not known if Mary Larson obtained additional information from Radian and the direct mail company. We will discuss at next week's call.

**ACTION: M. Larson to follow up with Radian and the direct mail company.**

**QC Process for Questionnaires**

Eric Larson indicated that the following items are checked:

- No duplicate subject nos.
- Ambiguous answers (e.g., circle not completely filled in, two answers filled in)
- Incorrect date

Eric indicated that of the errors he is seeing, 30-50% of them are duplicate answers. There no. of ambiguous answers is minimal. Eric also commented that for future questionnaires, the subject no. should be captured by the scantron sheet.

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Philip Morris would like further information on what the sites are checking for.

**ACTION:** M. Larson to discuss the sites' QC process of questionnaires next week.

**Frozen CRFs**

Philip Morris questioned why the no. of frozen CRFs was low. We explained that the edit checks were recently put in place and that this created queries for many of the frozen CRFs.

**ACTION: M. Larson to explain process of monitoring, freezing, and signing CRFs next week.**

**Overfilling Cells**

Philip Morris indicated that overfilling cells by 10% would be acceptable. Mary Westrick indicated that if the subject's information (BMI, tar level) provided to the call center is different when the subject arrives at a site, the subject will be disqualified. This will also help to minimize the overfilling of cells.

**Letter of Administrative Change**

Philip Morris will provide the exact wording for the LOAC that will further explain the exclusion criteria for people that have a conflict of interest (those individuals in litigation with tobacco companies). The call center will continue to exclude those individuals that have purchased cigarettes in Illinois. Philip Morris asked that we check with our IRB to confirm that an amendment is not needed and that a LOAC is acceptable.

**ACTIONS:**

**PM to provide wording for LOAC by 02/21/03.**

**M. Larson/T. Janisch to follow up with IRB.**

**Topography Downloads**

Eric Larson is contacting each site to make sure the topography files are being saved to the correct directories to allow the files to be transferred to etrials. Eric indicated that when the computers are returned to Covance he will also save the information to a disk. The disk would then be sent to the site to be maintained as source data.

**ACTION: E. Larson to notify J. Schultz when all the sites have been contacted.**

**Next Call**

Date: February 24, 2003

Time: 1:00 pm CT/2:00 pm ET

Password: CCS

Conference Leader: Jill Schultz

Toll Free No.: 877-269-7754 (domestic)  
201-689-7800 (international, if needed)

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